Application No.: 09/424, 686.

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

[X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

[X] 2. This application does not contain, as a separate part of the disclosure on paper copy, a Sequence Listing as required by 37 C.F.R. 1.821(c).

[ ] 3. A copy of the Sequence Listing in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

[X] 4. A copy of the Sequence Listing in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up Raw Sequence Listing.

[ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

[ ] 6. The paper copy of the Sequence Listing is not the same as the computer readable from of the Sequence Listing as required by 37 C.F.R. 1.821(e).

[ ] 7. Other: _____

Applicant Must Provide:

[X] An initial or **substitute** computer readable form (CRF) copy of the Sequence Listing.

[X] An initial or **substitute** paper copy of the Sequence Listing, as well as an amendment directing its entry into the specification.

[X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:
For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For Patent software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE

1652

PTO/SB/21 (12-97)
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TRANSMITTAL FORM

(To be used for all correspondence after initial filing)

Application Number	09/424,686
Filing Date	November 29, 1999
First Named Inventor	Gustav HAGEN
Group Art Unit	1652
Examiner Name	M. Walicka
Total Number of Pages in This Submission	
Attorney Docket Number	Bayer 10,203-KGB

ENCLOSURES (*check all that apply*)

☐ Fee Transmittal Form ☐ Fee Attached	☐ Assignment Papers *(for an Application)*	☐ After Allowance Communication to Group
☐ Amendment / Response ☐ After Final	☐ Drawing(s)	☐ Appeal Communication to Board of Appeals and Interferences
☐ Affidavits/declaration(s)	☐ Licensing-related Papers	☐ Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
☐ Extension of Time Request	☐ Petition	☐ Proprietary Information
☐ Express Abandonment Request	☐ To convert a Provisional Application	☐ Status Letter
☐ Information Disclosure Statement	☐ Power of Attorney, Revocation Change of Correspondence Address	☒ Additional Enclosure(s) -(please identify below):
☐ Certified Copy of Priority Document(s)	☐ Terminal Disclaimer	Response to Notice to Comply dated December 30, 2002; Diskette containing Sequence Listing; paper copy of Sequence Listing; copy of Notice to Comply dated December 30, 2002; return receipt postcard
☐ Response to Missing Parts/ Incomplete Application ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53	☐ Small Entity Statement ☐ Request for Refund	
	Remarks:	

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm *or* Individual name	**Theodore A. Gottlieb** **NORRIS McLAUGHLIN & MARCUS, P.A.**
Signature	**Reg. No. 42,597**
Date	January 30, 2003

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to : Hon. Assistant Commissioner of Patents, Washington, D.C. 20231, Box Sequence

Typed or printed name	Vilma I. Fernandez		
Signature		Date	January 30, 2003

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Hon. Commissioner of Patents, Washington, DC 20231.

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Bayer 0203-KBB/TAG

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,686	11/29/1999	GUSTAV HAGEN	BAYER10.203	8382

7590 12/31/2002

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EXAMINER
WALICKA, MALGORZATA A

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 12/31/2002

Petition & Response 1-30-03

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/424,686	Applicant(s) HAGEN ET AL.	
	Examiner Malgorzata A. Walicka	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08/19/02, 10/03/02 and 11/26/02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *13-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: withdrawal of finality of the last Office Action, indication of lack of compliance with requirements for sequence disclosures.

The Amendment under 37 CFR § 1.111 filed on August 19, 2002 as paper No. 20 is acknowledged. Paper No. 20 is a copy of the Amendment under 37 CFR § 1.111 mailed to the PTO on February 15, 2002 that did not reached the Office.

The Comments filed on October 3, 2002 and November 26, 2002 as paper No. 21 and 23 are acknowledged.

The amendments to the specification and claims have been entered as requested in paper No. 20. Claims 1-13 are canceled. New claims 14-46 are entered. Claims 14-46 are pending in the application and are the subject of this Office Action.

Detailed Office Action

1. Withdrawal of finality of the last Office Action

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn; the prosecution is reopened.

2. Restriction/election

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I: Claim 14 a), 15, 16, 24 in part, 25, 26, 34 in part, 35, 36, 44 in part, 45 in part, 46 in part, drawn to human catalytic telomerase subunit of SEQ ID NO: 2, its encoding DNA of SEQ ID NO: 1, expression vector, host cell and recombinant method of production of said catalytically active telomerase subunit.

Group II: Claim 14 b), 17, 24 in part, 27, 34 in part, 37, 44 in part, 45 in part, 46 in part, drawn to *Euplotes* p123 catalytic telomerase subunit, its encoding DNA, expression vector, host cell and recombinant method of production of said catalytically active telomerase subunit.

Group III: Claim 14 c), 18, 24 in part, 28, 34 in part, 38, 44 in part, 45 in part, 46 in part, drawn to *S. pombe* catalytic telomerase subunit, its encoding DNA, expression vector, host cell and recombinant method of production of said catalytically active telomerase subunit.

Group IV Claim 14 d), 19, 24 in part, 29, 34 in part, 39, 44 in part, 45 in part, 46 in part, drawn to human catalytic telomerase subunit wherein nucleotides 2345 to 2526 of its encoding DNA of SEQ ID NO: 1 are deleted, expression vector, host cell and recombinant method of production of said catalytically active telomerase subunit.

Group V: Claim 14 e), 20, 24 in part, 30, 34 in part, 40, 44 in part, 45 in part, 46 in part, drawn to human catalytic telomerase subunit, wherein nucleotides 2184 to 2219 of its encoding DNA of SEQ ID NO: 1 are deleted, expression vector, host cell and recombinant method method of production of said catalytically active telomerase subunit.

Group VI: Claim 14 f), 21, 24 in part, 31, 34 in part, 41, 44 in part, 45 in part, 46 in part, drawn to human catalytic telomerase subunit wherein nucleotides 2184 to 2219 and 2345 to 2526 of its encoding DNA of SEQ ID NO: 1 are deleted, expression vector, host cell and recombinant method of production of said catalytically active telomerase subunit.

Group VII: Claim 14 g), 22, 24 in part, 32, 34 in part, 42, 44 in part, 45 in part, 46 in part, drawn to human catalytic telomerase subunit wherein nucleotides 3219-3842 of its encoding DNA of SEQ ID NO: 1 have been replaced so that nucleotides 1783 to 3872 have the sequence of SEQ ID NO:7, expression vector, host cell and recombinant method of production of said catalytically active telomerase subunit.

Group VIII: Claim 14 h), 23, 24 in part, 33, 34 in part, 43, 44 in part, 45 in part, 46 in part, drawn to human catalytic telomerase subunit, wherein

its encoding DNA is a fragment of SEQ ID NO:1 consisting of nucleotides 60-3470, expression vector, host cell and recombinant method of production of said catalytically active telomerase subunit.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The special technical features of Groups I-VIII seems to be the catalytically active subunit of eucaryotic telomerase. However, the catalytically active subunit of eucaryotic telomerase of group I-IV, sequences recited by claim 14 a) to 14 d) are not contribution over the prior art, because they are disclosed in the US Patents No. 6,093,809; 6,309,867; and 6166,178, respectively.

The special technical features of Groups V-VIII seems to be a variant of the catalytically active subunit of human telomerase, however, each of the variant of Groups V-VIII is independent chemical entity having his own chemical structure and biologic properties. Thus, technical features of Group V-VIII are different. 37 CFR 1.475 does not provide for multiple products or methods within single application, therefore, unity of invention is lacking with regard to Group V-VIII. For the mentioned reasons restriction between Groups I-VIII is proper.

3. Lack of compliance of nucleotide sequence disclosure with 37 C.F.R. 1.821-1.825

Examiner acknowledges transmittal of Computer Readable Form (CFR) and Paper Sequence Listing on August 19, 2002. However, this application still fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons.

1. Sequences described in claim 14 a) to 14 h) should be identified by their specific sequence identification numbers and presented in full in the sequence listing.

2. The Paper Sequence Listing filed on August 19 comprises only 6 nucleic acid sequences, all of human origin, and claim 14 c) and 14 d) are directed to *Euplotes* and *S. pombe* sequences that are missing in the Paper Sequence Listing.

3. As such, sequences of human telomerase variants, claim 14 d)- 14 h) are unclear. The sequence listing lists the following nucleotide sequences:

SEQ ID NO: 1	*Homo sapiens*	4042 nucleotides
SEQ ID NO: 3	*Homo sapiens*	1153 nucleotides
SEQ ID NO: 4	*Homo sapiens*	413 nucleotides
SEQ ID NO: 5	*Homo sapiens*	1012 nucleotides
SEQ ID NO: 6	*Homo sapiens*	3972 nucleotides
SEQ ID NO: 7	*Homo sapiens*	2089 nucleotides.

Except for SEQ ID NO: 1 and 7 the sequences listed in the Paper Sequence Listing filed on August 19, 2002 are not in the accordance with sequences claimed in claim 14 b)-14h) and dependent claims.

Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Applicant is given ONE MONTH from the mailing date of this communication within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

4. Response to Applicants' Remarks

Applicants' arguments regarding rejection in the last Office Action, paper No. 10, of claims 1-5, 7, 10, 11 and 13, are currently moot, because all rejected claims are now cancelled and the request of restriction of the newly filed amended claims is issued; see paragraph 2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

Art Unit 1652

Patent Examiner